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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

PATEL, NIHIR B

ART UNIT	PAPER NUMBER
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3772

NOTIFICATION DATE	DELIVERY MODE
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04/30/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/823,475	Applicant(s) CHILDERS ET AL.	
	Examiner NIHIR PATEL	Art Unit 3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 25 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18, 19 and 21-43 is/are pending in the application.
4a) Of the above claim(s) 29-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18, 19, 21-28, 38-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Response to Amendment

1. The examiner acknowledges the amendment filed on September 25th, 2008. The amendment comprises amending claims 18, 26, 38 and 42; and cancelling claims 1-17 and 20.

Response to Arguments

2. Applicant's arguments with respect to claims **18, 19, 21-28 and 38-43** have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims **18, 19, 21-25 and 38-41** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim(s) contains subject matter, specifically "**and the valve is opened to create positive pressure throughout the reservoir**" and "**the positive pressure for the second maintenance mode being other than a pressure actuated by a piezo or thermal resistive element,**" which was not described in the specification in such a way as to reasonably

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convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, has possession of the claimed invention.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims **18, 19, 21, 26-28, 38, 42 and 43** are rejected under 35 U.S.C. 102(e) as being anticipated by Beavis et al. (US 7,146,977).

7. **As to claim 18**, Beavis teaches an apparatus that comprises a first pressurized supply of fluid **103B** in a reservoir **103** (**see fig. 1; col. 2 lines 55-65**); a fluid conduit from the supply to an ejector head and a valve **105** in the fluid conduit between the supply and the head (**see fig. 1**), a programmable controller **104** wherein the reservoir, the fluid conduit, and the ejector head form a fluidically connected fluid delivery unit controlled by the programmable controller and capable of operating in a first operational mode and a second maintenance mode (**see col. 3**); wherein, in the first operational mode of the fluid delivery unit, the ejector head is operable to deliver fluid from the reservoir through the ejector head, the fluid in the ejector head and the fluid conduit being at a lower pressure relative to the fluid in the reservoir; and wherein, in the second maintenance mode of the fluid delivery unit, the ejector head is disabled and the valve is opened to create positive pressure throughout the reservoir, the fluid conduit and the reservoir head, the

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positive pressure purging out all remaining fluid from the fluid delivery unit by way of the disabled ejector head, the positive pressure for the second maintenance mode being other than a pressure actuated by a piezo or thermal resistive element (**see cols. 2 and 3**).

8. **As to claim 19**, Beavis teaches an apparatus that comprises pressure regulation apparatus in the reservoir to maintain the supply of fluid in a pressurized state (**see col. 3 lines 1-15**).

9. **As to claim 21**, Beavis teaches an apparatus that comprises a sensor means for monitoring an operational aspect of the ejector head (**see col. 3 lines 15-25**).

10. **As to claim 26**, Beavis teaches an apparatus that comprises a first pressurized supply of fluid **103B** in a reservoir **103** (**see fig. 1; col. 2 lines 55-65**); a fluid conduit from the supply to an ejector head and a valve **105** in the fluid conduit between the supply and the head (**see fig. 1**), a programmable controller **104** capable of operating the delivery apparatus in a first operational mode wherein the ejector head is operable to deliver fluid from the supply through the ejector head, and in a second maintenance mode wherein the ejector head is disabled and fluid is purged through the ejector head; and pressurized supply of fluid in a reservoir, a fluid conduit from the second pressurized supply of fluid to the ejector head, and a valve in the fluid conduit (**see cols. 2 and 3**).

11. **As to claim 27**, Beavis teaches an apparatus wherein the fluid in the first pressurized supply of fluid comprises a medication (**see col. 2 lines 50-65**).

12. **As to claim 28**, Beavis teaches an apparatus wherein the fluid in the second pressurized supply of fluid comprises a maintenance fluid (**see col. 3 lines 60-67**).

13. **As to claim 38**, Beavis teaches an apparatus that comprises an ejector head (**see fig. 1**); a pressurizable supply of fluid **103B** in a reservoir **103** (**see fig. 1; col. 2 lines 55-65**), the reservoir

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having a pressure regulation apparatus that supplies fluid to the ejector head at a controllable pressure (**see col. 3 lines 10-20**); a fluid conduit from the reservoir to the ejector head and a valve **105** in the fluid conduit between the reservoir and the ejector head (**see fig. 1**); and a control system **104**; wherein the reservoir, the fluid conduit, and the ejector head form a fluidically connected fluid delivery unit controlled by the control system (**see fig. 1; col. 3**), the control system being configured to control the fluid supply system in two different modes including an operating mode wherein the fluid is supplied to the ejector head with an operational pressure, such that the fluid in the ejector head and the fluid conduit are at a lower pressure relative to the fluid in the reservoir and an ejector head purge mode wherein the ejector head is disabled and the valve is opened to create positive pressure throughout the reservoir, the fluid conduit and the ejector head, the positive pressure purging out all remaining fluid from the fluid delivery unit by way of the disabled ejector head, the positive pressure for the ejector head purge mode being other than a pressure actuated by a piezo or thermal resistive element (**see fig. 1; cols. 2 and 3**).

14. **As to claim 42**, Beavis teaches an apparatus that comprises an ejector head (**see fig. 1**); a fluid supply system having a pressure regulation apparatus that supplies fluid **103B** to the ejector head at a controlled pressure (**see fig. 1 col. 3**); and a control system **104** configured to control the fluid supply system in two different modes including an operating mode wherein the fluid is supplied to the ejector head with an operational pressure; and an ejector head purge mode wherein the fluid supply pressure is at a purge pressure that is different from the operational pressure (**see fig. 1; col. 3**); wherein the fluid supply system includes first **103B** and second fluids **110**, and wherein the control system is configured for supplying the first fluid to the

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ejector head in the operating mode And the second fluid to the ejector head in the ejector head purge mode (**see fig. 1; cols. 2 and 3**).

15. **As to claim 43**, Beavis teaches an apparatus in which the first fluid comprises a medication and the second fluid comprises a maintenance fluid (**see fig. 1; cols. 2 and 3**).

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

18. Claims **22-24** are rejected under 35 U.S.C. 103(a) as being unpatentable over Beavis et al. (US 7,146,977) in view of Poole (US 6,158,431).

19. **As to claims 22 and 23**, Beavis substantially discloses the claimed invention; see rejection of claim 18 above, but does not disclose a sensor means (temperature sensor capable of measuring the temperature of a portion of the ejector head controlled by the programmable controller) for monitoring an operational aspect of the ejector head. Poole teaches an apparatus

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that does provide a sensor means (temperature sensor capable of measuring the temperature of a portion of the ejector head controlled by the programmable controller) for monitoring an operational aspect of the ejector head (**see col. 12 lines 60-67**). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Beavis's invention by providing a sensor means (temperature sensor capable of measuring the temperature of a portion of the ejector head controlled by the programmable controller) for monitoring an operational aspect of the ejector head as taught by Poole in order to provide more accurate dose of medicament and to prevent the liquid from jamming the ejector head.

20. **As to claim 24**, Beavis substantially discloses the claimed invention; see rejection of claim 18 above, but does not disclose a sensor means that comprises a counter for counting the number of times that the ejector head has been activated. Poole teaches an apparatus that does provide a sensor means that comprises a counter for counting the number of times that the ejector head has been activated (**see col. 13 lines 1-13**). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Beavis's invention by providing a sensor means that comprises a counter for counting the number of times that the ejector head has been activated as taught by Poole so that the user knows a head of time when to replace the pressurized fluid reservoir.

21. Claims **25 and 39-41** are rejected under 35 U.S.C. 103(a) as being unpatentable over Beavis et al. (US 7,146,977) in view Koerner et al. (US 2004/0195352).

22. **As to claim 25**, Beavis substantially discloses the claimed invention; see rejection of claim 18 above, but does not disclose a clock for measuring the time interval from a prior

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maintenance mode. Koerner teaches an apparatus that comprises a clock for measuring the time interval from a prior maintenance mode (**see paragraph [0023]**). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Beavis's by providing a clock for measuring the time interval from a prior maintenance mode as taught by Koerner in order to provide medication to the patient at a proper time interval.

23. **As to claim 39**, Beavis substantially discloses the claimed invention; see rejection of claim 38 above, but does not disclose an apparatus wherein the ejector head that includes thermal drop generators. Koerner discloses an apparatus wherein the ejector head includes thermal drop generators (**see figure 1; paragraph [0023]**). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Beavis's by providing an apparatus wherein the ejector head that includes thermal drop generators as taught by Koerner so that any liquid residues present evaporate and are discharged.

24. **As to claim 40**, Beavis substantially discloses the claimed invention; see rejection of claim 38 above, but does not disclose an apparatus wherein the fluid at the operational pressure is at a negative gauge pressure. Koerner discloses an apparatus wherein the fluid at the operational pressure is at a negative gauge pressure (**see paragraph [0021]**). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Beavis's by providing an apparatus wherein the fluid at the operational pressure is at a negative gauge pressure as taught by Koerner in order to provide medication to a patient with the correct amount of pressure.

25. **As to claim 41**, Beavis substantially discloses the claimed invention; see rejection of claim 38 above, but does not disclose an apparatus wherein the fluid at the purge pressure is at a

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positive gauge pressure. Koerner teaches an apparatus wherein the fluid at the purge pressure is at a positive gauge pressure (**see paragraph [0021]**). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Beavis's by providing an apparatus wherein the fluid at the purge pressure is at a positive gauge pressure as taught by Koerner in order to remove any residues remaining within the system.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIHIR PATEL whose telephone number is (571)272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Nihir Patel/

Examiner, Art Unit 3772

/Patricia Bianco/

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